II. REMARKS

Claims 1-13 were pending. Claims 14-23 were canceled in the parent case pursuant to a restriction requirement. The pending claims are directed to methods of nucleic acid immunization. The claims have been amended herein to recite "gene delivery vehicle" and new claims 24 and 25 have been added. Support for the amendment can be found for example on page 25, line 25. The amendment is made solely to expedite prosecution, is not intended in any way as an acknowledgment as to the correctness of the Examiner's position, and is made for reasons unrelated to patentability.

In view of the foregoing amendments, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: 7/27/01 By: _____

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Version Showing Changes Made

1. (Amended) A method for treating intracellular infections with warm-blooded animals, comprising:

(a) administering to a warm-blooded animal a [vector construct which directs the expression of] gene delivery vehicle comprising a polynucleotide encoding at least one immunogenic portion of an antigen derived from an intracellular pathogen; and

(b) administering to said warm-blooded animal a protein which comprises said immunogenic portion of said antigen, such that an immune response is generated.

3. (Amended) The method according to claim 1, wherein said protein is administered prior to administration of said [vector construct] gene delivery vehicle.

5. (Amended) The method according to claim 3, wherein said viral antigen is obtained from a virus selected from the group consisting of hepatitis, feline immunodeficiency virus (FIV), and human immunodeficiency virus (HIV) [HIV].

11. (Amended) The method according to claim 1, wherein said [vector construct] gene delivery vehicle is [carried by] a recombinant retrovirus.

12. (Amended) The method according to claim 1, wherein said [vector construct is carried by a recombinant virus] gene delivery vehicle is selected from the group consisting of alphaviruses, adeno-associated virus and parvovirus.

13. (Amended) The method according to claim 1, wherein said [vector construct] gene delivery vehicle is a nucleic acid expression vector, or a eukaryotic layered vector initiation system.

14. (Amended) A composition. comprising a [vector construct which directs the expression of] gene delivery vehicle comprising a polynucleotide encoding at least one immunogenic portion of an antigen derived from an intracellular pathogen, a protein which comprises said immunogenic portion of said antigen, and a pharmaceutically acceptable carrier or diluent.

17. (Amended) The composition according to claim 16, wherein said viral antigen is obtained from a virus selected from the group consisting of hepatitis, feline immunodeficiency virus (FIV), and human immunodeficiency virus (HIV) [HIV].

23. (Amended) The composition according to claim 1, wherein said [vector construct is carried by] gene delivery vehicle is a recombinant retrovirus.

24. (New) The method of claim 1, wherein the gene delivery vehicle comprises naked DNA.

25. (New) The composition of claim 1, wherein the gene delivery vehicle comprises naked DNA.

Currently Pending Claims

In the claims:

1. A method for treating intracellular infections with warm-blooded animals, comprising:

(a) administering to a warm-blooded animal a gene delivery vehicle comprising a polynucleotide encoding at least one immunogenic portion of an antigen derived from an intracellular pathogen; and

(b) administering to said warm-blooded animal a protein which comprises said immunogenic portion of said antigen, such that an immune response is generated.

2. The method according to claim 1, further comprising the step of administering an immunomodulatory cofactor.

3. The method according to claim 1, wherein said protein is administered prior to administration of said vector construct.

4. The method according to claim 1, wherein said intracellular pathogen is virus and said antigen a viral antigen.

5. The method according to claim 3, wherein said viral antigen is obtained from a virus selected from the group consisting of hepatitis, feline immunodeficiency virus (FIV), and human immunodeficiency virus (HIV).

6. The method according to claim 5, wherein said antigen is a hepatitis B antigen.

7. The method according to claim 6, wherein said hepatitis B antigen is selected from the group consisting of HBeAg, HBcAg and HbsAg.

8. The method according to claim 5 wherein said antigen is a hepatitis C antigen.

9. The method according to claim 8 wherein said hepatitis C antigen is selected from the group consisting of core antigen C, E 1, E2/NS1, NS2, NS3, NS4 and NS5.

10. The method according to claim 1, wherein said intracellular pathogen is a parasite.

11. The method according to claim 1, wherein said gene delivery vehicle is [carried by] a recombinant retrovirus.

12. The method according to claim 1, wherein said gene delivery vehicle is selected from the group consisting of alphaviruses, adeno-associated virus and parvovirus.

13. The method according to claim 1, wherein said gene delivery vehicle is a nucleic acid expression vector, or a eukaryotic layered vector initiation system.

14. A composition. comprising a gene delivery vehicle comprising a polynucleotide encoding at least one immunogenic portion of an antigen derived from an intracellular pathogen, a protein which comprises said immunogenic portion of said antigen, and a pharmaceutically acceptable carrier or diluent.

15. The composition according to claim 14, further comprising an imunomodulatorv cofactor.

16. The composition according to claim 14, wherein said intracellular pathogen is a virus, and said antigen a viral antigen.

17. The composition according to claim 16, wherein said viral antigen is obtained from a virus selected from the group consisting of hepatitis, feline immunodeficiency virus (FIV), and human immunodeficiency virus (HIV).

18. The composition according to claim 16, wherein said antigen is a hepatitis B antigen.

19. The composition according to claim 18, wherein said hepatitis B antigen is selected from the group consisting of HBeAg, HBcAg and HbsAg.

20. The composition according to claim 16, wherein said antigen is a hepatitis C antigen.

21. The composition according to claim 20, wherein said hepatitis C antigen is selectedfrom the group consisting of core antigen C, El, E2/NS1, NS2, NS3, NS4 and NS5.

22. The composition according to claim 14, wherein said intracellular pathogen is a parasite.

23. The composition according to claim 1, wherein said gene delivery vehicle is a recombinant retrovirus.

24. (New) The method of claim 1, wherein the gene delivery vehicle comprises naked DNA.

25. (New) The composition of claim 1, wherein the gene delivery vehicle comprises naked DNA.